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The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on DuPont's HPV Test Plan and Robust Summary for the Dicarboxylic Acid Category

Dear Administrator Whitman:

The following comments on the DuPont test plan for the dicarboxylic acid category are submitted on behalf of the Physicians Committee for Responsible Medicine (PCRM), People for the Ethical Treatment of Animals (PETA), the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

DuPont has appropriately developed a category of three, straight-chained, aliphatic dicarboxylic acids, which include adipic acid (CAS #124-04-9), glutaric acid (CAS #110-94-1), and butanedoic acid (CAS #110-15-6). The test plan and robust summaries show that the three category members have comparable physical, chemical, and toxicological properties and exhibit trends with increasing molecular weight. These chemicals are byproducts in the manufacture of cyclohexanol, but also have other applications, such as use as food additives and perfume fixatives.

DuPont has provided a thorough presentation of available information and has included monitoring data, manufacture, exposure, and use information on the dicarboxylic acids. We commend this submission, as this type of information has been glaringly absent from other HPV test plans.

However, DuPont has proposed to conduct a reproductive toxicity test with adipic acid. This test plan is inappropriate because adequate information already exists to satisfy the SIDS endpoint for reproductive toxicity, and adipic acid is already regulated by the Food and Drug Administration (FDA) as a Generally Recognized as Safe (GRAS) chemical. Other dicarboxylic acids may be tested based on the results of this proposed test on adipic acid. This plan could result in the death of nearly 1,000 animals.

The plan therefore violates the following two terms of the October 1999 Agreement among the EPA, industry, and health, animal protection, and environmental organizations, which states, in part:

1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

8. In analyzing the adequacy of screening data for chemicals that are substances Generally Recognized as Safe (GRAS) for a particular use by the Food and Drug Administration (FDA), participants should consider all relevant and available information supporting the FDA's conclusions. Participants reviewing the adequacy of existing data for these chemicals should specifically consider whether the information available makes it unnecessary to proceed with further testing involving animals. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.

"In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach."

Adequate information already exists to satisfy the SIDS endpoint for reproductive toxicity. DuPont presented data in its robust summary on all SIDS endpoints except reproductive toxicity. However, developmental and repeat dose studies have already been conducted on animals, and no adverse reproductive effects were observed in the repeat dose tests. Since the HPV program is based almost exclusively on animal testing information—regardless of its relevance and reliability—this information should be sufficient to satisfy the SIDS endpoints under the HPV program.

The main health concerns with exposure to these compounds are irritancy effects. DuPont has already conducted these experiments on animals and presented animal data for these endpoints. Further testing on animals will not provide any meaningful data or expand the knowledge of the potential hazards of these chemicals.

"As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant."

Adipic acid, an FDA GRAS chemical, is used in the manufacture of pharmaceuticals and as a perfume fixative. It also has been accepted as a food additive and can be found in non-alcoholic beverages, gelatins, and puddings. It is used as an acidulant in dry powdered food mixtures, powdered drink mixes, bottled beverages, canned vegetables, flavoring agents, candies, and throat lozenges. It may also be used as an agent to improve the melting characteristics of cheese and to increase whipping quality.

Existing data suggest that the dicarboxylic acids do not present a hazard from low-level, chronic exposure. In general, the main health hazard posed by aliphatic dicarboxylic acids is dermal and ocular irritation as well as dust explosion hazards. Subsequently, DuPont has an occupational safety and health plan in place and closely monitors exposure to adipic acid. Human exposure to these chemicals is clearly limited. The proposed test chemical, adipic acid, is already regulated by the FDA and has been labeled GRAS as a food additive. The proposed reproductive studies will not change the way the material is handled or advance the understanding of the health hazards of dicarboxylic acids.

Thank you for your attention to these comments. I can be reached at 202-686-2210, ext. 302, or via e-mail at *ncardello@pcrm.org*.

Sincerely,

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Staff Scientist